Response to Office Action dated November 22, 2005

#### REMARKS

### Status of the Claims

Claims 1, 4-7, 9-23 and 25-27 are pending with entry of this amendment, claims 2-3, 8 and 28-53 begin canceled herein. Claims 1, 4-7, 9-12 and 25 are amended herein. These amendments introduce no new matter and support is replete through the specification. Support for claims 1, 4-7, 9-12 is found at least at page 8, lines 28-33, and Figure 1. Support for claim 25 is found at least at page 4, lines 20-24. These amendments are made to more particularly point out and distinctly claim the subject matter. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record. Entry of the Amendment is respectfully requested.

#### Objections to the Drawings

The drawings were objected to as being informal due to the hand written figure designations. Office Action page 3. Applicants point out that the drawings were objected upon initial examination of the instant case (see PAIR: Notice to File Missing Parts dated September 20, 2001). In response to the formalities notice, Applicant submitted formal drawings that contained appropriate margins and corrected for the hand written figure designations (see Applicant's response dated November 19, 2001; PAIR entry 1/23/2002, "Applicant Response to Pre-Exam Formalities Notice," page 4). Applicants include herewith a copy of the stamped receipt indication postcard that further corroborates the filing of formal drawings (see Attachment A).

To facilitate prosecution of the instant case, Applicants provide herewith a courtesy copy of the Letter to the Official Draftsperson as well as a copies of the formal drawings (see Attachment B) as filed on November 19, 2001. In light of the foregoing, Applicants request that objection to the drawings be withdrawn.

#### Objection to Claim 8

Claim 8 was objected to as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicants have canceled claim 8. Therefore, the objection to claim 8 is most.

Response to Office Action dated November 22, 2005

### Rejection Under 35 USC 112, second paragraph

Claim 26 was rejected as allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is asserted that Claim 26 is indefinite because it is unclear what the metes and bounds of "a nucleotide sequence of SEQ ID NO: 1 encompasses" and that it is "unclear what functional relationship a nucleotide sequence of SEQ ID NO: 1 has in the expression cassette used in the method of claim 1..." Office Action page 4. Applicants respectfully traverse the rejection.

In the instant application, Applicants provide a working example of one embodiment of the invention (see pages 18 through 27). SEQ ID NO: 1 constitutes the final construct prepared in the working example, pFP-IRN1, which corresponds to the schematic presented in Figure 1 (see page 24, line 16). More specifically, SEQ ID NO: 1 is an expression construct that comprises the figwort mosaic virus promoter (page 19, line 28) operably linked to the polygalacturonase (PG) gene (the targeting sequence) and an inverted repeat sequence situated 3' of the PG gene. The inverted repeat sequence contained in SEQ ID NO: 1 comprises an inverted nopaline synthase (NOS) terminator sequence (the antisense element) linked to a downstream sense NOS terminator sequence (the sense element) (page 19, lines 4-6). Once SEQ ID NO: 1 is transcribed, the sense and antisense elements contained in the inverted repeat sequence become incorporated into the transcript for the PG gene; and, the sense and antisense elements bind to form a double stranded RNA which targets the entire transcript for degradation.

From the teaching in the specification, it is clear what the nucleotide sequence of SEQ ID NO: 1 encompasses, and its functional relationship to the method of Claim 1 is equally clear. Applicants submit that Claim 26 is proper in its current form. Accordingly, Applicants request that the rejection to Claim 26 be withdrawn.

# Rejection Under 35 USC 112, first paragraph

Claims 1-23 and 25-27 were rejected because the specification allegedly does not reasonably provide enablement wherein the inverted repeat is operably linked 5' of the targeting sequence. Office Action page 4. Applicants have canceled Claims 2-3 and have amended Claim 1 to recite that the inverted repeat in a position 3' to the targeting sequence. Accordingly, this rejection is moot.

Claims 1-23 and 25-27 were also rejected because the specification allegedly does not reasonably provide enablement wherein the inverted repeat is prepared from any subsequence of nopaline synthase gene. Office Action page 4. It is further asserted that one of skill in the art would recognize that 5' untranslated regions of any gene would not have the ability to form a double stranded RNA in the cell. Office Action page 5. Applicants respectfully traverse this rejection.

Appl. No. 09/924,197

Response to Office Action dated November 22, 2005

Applicants point out that it is the interaction of the antisense element and the sense element contained in the inverted repeat sequence that, upon transcription, forms the double stranded RNA. Therefore, an inverted repeat sequence as claimed herein containing a sense element comprising the 5' untranslated region of the NOS gene, as well as an antisense element comprising a reverse complement of the sense element would form double stranded RNA upon transcription. And, in light of the teachings in the instant application, it would not take one skilled in the art undue experimentation to practice the invention. Accordingly, withdrawal of this rejection is respectfully requested.

# **CONCLUSION**

In view of the foregoing, Applicants believe that all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (510) 259-6115.

Respectfully submitted,

MENDEL BIOTECHNOLOGY, INC.

Date: February 22, 2005

Suzanne Mack Reg. No. 44.888

21375 Cabot Boulevard Hayward, California 94545 Phone: (510) 259-6120

Fax: (510) 264-0254

SAM/sam

File; MBI-0080US.ROA.02222005.doc